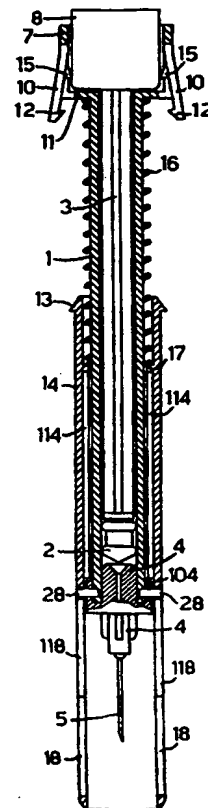




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61M 5/32</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/35714</b> <b>(43) International Publication Date:</b> 20 August 1998 (20.08.98)
<b>(21) International Application Number:</b> PCT/EP98/00692 <b>(22) International Filing Date:</b> 9 February 1998 (09.02.98)  <b>(30) Priority Data:</b> SV97A000007      12 February 1997 (12.02.97)      IT SV97A000008      12 February 1997 (12.02.97)      IT  <b>(71)(72) Applicants and Inventors:</b> RESTELLI, Sergio [IT/IT]; Via Giacinta Pezzana, 9, I-00197 Roma (IT). RIGHI, Nardino [IT/IT]; Viale Padova, 314, I-20132 Milano (IT).  <b>(74) Agent:</b> KARAGHIOSOFF, Giorgio, A.; Via Pecorile, 27/B, I-17015 Celle Ligure (IT).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>
<b>(54) Title:</b> DISPOSABLE SAFETY SYRINGE  <b>(57) Abstract</b> <p>The syringe is provided with a needle-covering sleeve (14), which is slidably fitted on the syringe barrel (1) and is held in its retracted rest position by means of retaining tongues (10), which hook its rear rim (13). At the end of the injection stroke of the plunger (2), a rear head (8) of the stem (3) of the plunger (2) radially opens the retaining tongues (10) apart, which release thereby the needle-covering sleeve (14). Then, the latter is axially advanced by a spring (16), until it entirely covers the needle (5). The needle-carrier (4, 104) has at least one lateral locking projection (28), slidably engaging in a longitudinal slot (18), which is formed in the needle-covering sleeve (14) and is delimited at its sides, at least in its progressively tapering rear end (118), by two convergent and elastically openable stop sticks (19) which allow the passage of the locking projection (28) between their free ends, but then point against it and fasten it to the needle-covering sleeve.</p>		



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Larvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

### Disposable safety syringe

5           The present invention relates to a disposable safety syringe, comprising:

          a) a cylindrical syringe barrel;

          b) an injection needle, being integral with a needle-carrier, which is attached to the fore end of  
10   the syringe barrel;

          c) a plunger which is slidable in the syringe barrel and has an injection stroke which extends from a retracted utmost syringe-filling position, wherein the liquid medicine has been aspired, to a forwardmost  
15   position, and is fitted at its back with a manually drivable stem, driven out of the syringe barrel through the open rear end thereof;

          d) a needle-covering sleeve, which is axially fitted on the syringe barrel, so as to slide from a retracted rest position, in which it leaves the needle exposed, into an advanced safety position, in which it  
20   entirely covers the needle;

          e) plunger-clamping means, consisting of hook-like interacting means, which are provided at the rear side  
25   of the syringe barrel and at the rear side of the needle-covering sleeve, and are initially engaged with each other so as to retain the needle-covering sleeve in its retracted rest position, whereas they are automatically disengaged from each other by the plunger  
30   stem, in the last portion of the injection stroke of

CONFIRMATION COPY

the plunger, thereby releasing the needle-covering sleeve;

f) a spring, interposed between the rear of the syringe barrel and the needle-covering sleeve, which stresses the needle-covering sleeve, once it is released from the hook-like means, towards its advanced safety position, first by making it elastically adhere to the patient body, and then by progressively advancing it, on extracting the needle from the patient body, at the end of the injection, until it entirely covers the extracted needle.

The invention has the object to provide a disposable safety syringe of the type described hereinbefore, which has a simpler and cheaper construction and an easier and safer operation.

This object is achieved by the invention with a disposable safety syringe of the type described hereinbefore, in which:

g) the needle-covering sleeve has a rear rim having the shape of an outwardly projecting hook-like tooth, cooperating with one or more complementary inwardly projecting hook-like teeth, provided on retaining tongues, which extend forwardly in the longitudinal direction of the syringe from a head located at the rear end of the syringe barrel and are automatically movable from a radially retracted hooking position, in which their teeth hook the rim of the needle-covering sleeve, holding it in its retracted rest position, into a radially opened out releasing position, in which their teeth are released from the

rim of the needle-covering sleeve and disengage it;

h) the rear end of the plunger stem is provided with means which cooperate with the retaining tongues and automatically cause these tongues to move from  
5 their radially retracted hooking position, into their radially opened out releasing position, at the end of the injection stroke of the plunger;

i) the needle-carrier has at least one lateral locking projection, which projects radially outwards,  
10 and slidably engages in a longitudinal slot, formed in the needle-covering sleeve, whereas, at the rear end of said slot, there are provided automatic stop means, engaging said lateral locking projection, preventing any axial movement thereof with respect to the needle-  
15 covering sleeve, in the advanced safety position thereof, thus securing at least the needle-carrier to the needle-covering sleeve.

The syringe according to the invention is provided with an automatic needle coverage, the needle-covering  
20 sleeve, which is released from the plunger stem when the latter, at the end of the injection, reaches the end-of-stroke position, for injecting the medicine. Once the needle of the syringe has been extracted from the muscle or vein of the patient and, at the latest,  
25 once the pressure of the syringe-controlling fingers has been released, the needle-covering sleeve immediately and automatically covers the needle, locking it therein. Any attempt to remove the needle protection would cause it to be torn away from the  
30 syringe, therefore the needle would be well protected

ad locked in its protective needle-covering shell.

A preferred embodiment of the syringe according to the invention is based on the acknowledgement that the needle-covering sleeve, which is only free to snap forwardly to its advanced safety position, when the syringe plunger has run the whole injection stroke, cannot prevent the syringe from being used for more than one user, by injecting each one with only a part of the total volume of liquid, aspirated by the syringe. Therefore, said embodiment of the invention is aimed at providing a disposable safety syringe which ensures the prevention of a shared use thereof, causing the needle-covering sleeve to snap forwardly to its needle-covering position, even when smaller doses of the maximum contents of the syringe are injected.

The invention achieves the above objects by providing a syringe according to claim 1, further having the following characteristics:

k) the cooperating plunger-clamping means, provided at the rear end of the plunger stem and of the syringe barrel are arranged to fasten the plunger stem to the syringe barrel, so as to prevent it from being unlocked in either direction;

l) the plunger stem and the syringe barrel are provided at their rear end with cooperating safety means, which are manually removable or disengageable, and initially (in the syringe supplied condition) prevent any forward movement of the plunger stem, retaining it in a rest or starting position, in which the plunger-clamping means, on the plunger stem and on

the syringe barrel are disengaged from each other and from which position the plunger stem may be caused to run (once the safety means have been released) a terminal forward stroke, substantially corresponding to the minimum medicine dose which can be injected by the syringe, and thereafter the plunger-clamping means on the plunger stem and on the syringe barrel engage with each other and secure the plunger stem to the syringe barrel,

- 10           m) the plunger stem has a length between
- a maximum length, wherewith, in the initial rest position of the plunger stem, the fore end of the plunger is set back from the bottom of the syringe barrel, at a distance substantially corresponding to the above mentioned terminal forward stroke of the plunger stem, and the greatest quantity of medicine that can be injected by the syringe corresponds to the quantity drawn in, and
  - 15           - a minimum length, wherewith, in the initial rest position of the plunger stem, the fore end of the plunger is set back from the bottom of the syringe barrel, at a distance substantially corresponding to the longest possible further backward stroke of the plunger, from this position to the retracted utmost syringe-filling i.e. aspirating position and the greatest quantity of medicine that can be injected by the syringe substantially corresponds to the
  - 20           terminal forward stroke of the plunger stem
  - 25
  - 30

(smallest injectable dose).

Advantageously, the syringe is associated to a package of liquid medicine, and the stem of its plunger has such a length that the maximum syringe-filling  
5 volume of medicine which can be aspirated is at the most equal to the volume of the medicine contained in the package or preferably smaller.

Syringes for injecting predetermined medicine doses, or smaller, may be provided with stems having a  
10 corresponding fixed length, and being by turns fitted in the syringe barrel during the syringe manufacturing process.

The stem may be advantageously provided with a variable length, for example with a telescopic  
15 adjustment.

The advantages of the present invention are apparent from the above description. By a single type of syringe, the problem related to the shared use of syringes may be obviated, particularly when the doses  
20 to be injected are smaller than the utmost filling dose. Particularly, when syringes are sold together with the medicine, the length of the plunger may be determined in such a way as to only allow a predetermined dose of medicine to be injected. The dose  
25 allowed to be injected before the plunger is clamped and the needle-covering sleeve snaps into the operating position, rendering the syringe unusable, may vary between a maximum dose, corresponding to the greatest volume of liquid that can be aspirated, and the  
30 smallest injectable dose, which corresponds to the



volume defined by the terminal stroke of the plunger between the starting position and the position in which the plunger and the plunger-clamping means are mutually engaged. This injectable dose may be determined by simply providing plunger stems having correspondingly different lengths. The telescopic construction of the stem allows for the use of a single stem for all types of syringe, reducing manufacturing costs and limiting any possible increase thereof only to one additional part of stem.

Even though the syringe according to the invention requires the quantity of the aspirated medicine to be slightly greater than the injectable quantity, the costs involved by a certain limited quantity of non consumable medicine are not comparable to public health costs involved by people suffering from serious infections, the latter being much more burdensome to the community. This is especially remarkable in geographical areas in which public health is significantly supported by solidarity organizations, such as the World Health Organization, and others, since the small immediate higher expense for the unusable medicine is largely compensated by the savings obtained by limiting the infection rate due to the shared use of syringes.

These characteristics of the invention and others, as well as the advantages derived therefrom will appear more clearly from the following disclosure of certain preferred embodiments, illustrated not by way of restriction in the accompanying drawings, in which:

Fig. 1 is an axial rear end view of a first embodiment of the disposable safety syringe according to the invention.

Fig. 2 is a lateral elevational view of the syringe, in the direction of arrows II-II in figs. 1 and 3, and in the initial condition.

Fig. 3 is an axial sectional view of the syringe, taken on lines III-III in figs. 1 and 2 and in the same initial condition.

Figs. 4 and 5 show the syringe in a view corresponding to fig. 2 and in a longitudinal sectional view corresponding to fig. 3, but in the final condition, when the injection has been executed and the needle has been extracted from the patient body.

Fig. 6 is an exploded perspective view of a further embodiment of the syringe according to the present invention.

Fig. 7 is a lateral elevational view of the syringe according to fig. 6, in the assembled condition and with operating safety means.

Fig. 8 is an axial sectional view of the syringe according to fig 7, having the longest possible stem.

Fig. 9 is an axial sectional view of the syringe according to fig. 8, with the plunger being in the end-of-stroke condition.

Fig. 10 is a cross sectional view of the telescopically extensible stem.

Fig. 11 is a view of the syringe according to the invention as in figure 8, in the version with the shortest possible stem, and with operating safety

means.

Fig. 12 is a view of the syringe as in fig. 11, when the liquid to be injected has just been aspirated.

Fig. 13 is a view of the syringe as in figs. 11  
5 and 12, when air has just been discharged therefrom.

Fig. 14 is a view of the syringe as in figures 11 to 13, when a predetermined quantity of liquid, smaller than the drawn in quantity, has just been injected, with the plunger-clamping and needle-covering means in  
10 the operating condition.

In the embodiment according to figs. 1 to 5, the disposable safety syringe according to the invention comprises a cylindrical barrel 1, in which a plunger 2 is slidable in a fluid-tight manner. The plunger 2 is  
15 attached to a stem 3, which extends axially in the syringe barrel 1 and is driven out of it, through its open rear end. At the fore end of the syringe barrel 1, a needle-carrying member 4 is attached in a fluid-tight manner, the injection needle 5 being fixed thereto. In  
20 the illustrated embodiment, the needle-carrier 4 is engaged in the fore end of the syringe barrel 1 like a plug, and has an outward flap 104 covering the fore end of the syringe barrel 1. The inner space of the syringe barrel 1 communicates with the tubular injection needle  
25 5, through a hole formed in the needle-carrier 4. The needle 5 is initially protected by a cap 6, fitted on the needle-carrier 4.

The syringe barrel 1 is provided, at its rear end, with two radial diametrically opposite tabs 11, and a  
30 widened, hollow head 7 open at its back, wherein a head

8, provided at the rear end of the stem 3 of the plunger 2 may be inserted. In two diametrically opposite locations, two retaining tongues are formed on the sidewall of the head 7 of the syringe barrel 1, by means of cuts 9, and extend forwardly in the longitudinal direction beyond the fore edges of the head 7 and of the radial tabs 11 of the syringe barrel 1. At their free fore ends, the retaining tongues 10 have each one hook-like tooth 12, which is turned radially inwardly and cooperates with the rear rim, having the shape of a hook-like tooth 13, turned radially outwardly, of a needle-covering sleeve 14, which is slidably axially fitted on the syringe barrel 1. Normally, in the rest condition, the retaining tongues 10 lie in a radially retracted position, i.e. substantially parallel to the longitudinal axis of the syringe, and in which their hook-like teeth 12 are engaged with the rim, formed with a hook-like counter-tooth, of the needle-covering sleeve 14, as shown in fig. 3. However, said retaining tongues 10 may be radially outwardly opened apart and brought to a position, in which their hook-like teeth 12 disengage from the rim, having the shape of a hook-like counter-tooth, of the needle-covering sleeve 14, as shown in fig. 5.

In order to obtain said radial deflection of the retaining tongues, each retaining tongue 10 is provided - on its radial inner side - with a projection 15, protruding inside the hollow head 7 of the syringe barrel 1 and having a surface which is inclined in the

rear-front direction towards the center axis of the syringe. These slanted inner projections 15 of the retaining tongues 10 cooperate with the fore rim (preferably rounded) and with the sidewall of the head 5 8 of the stem 3 of the plunger 2, as described hereafter.

For a certain length of its rear end part, the inside diameter of the needle-covering sleeve 14 is greater than the outside diameter of the syringe barrel 10 1, and the cylindrical hollow space resulting therefrom houses a helical spiral spring 16, which bears by its rear end against the radial tabs 11 of the syringe barrel 1 and against the bottom of the hollow head 7 of the syringe barrel 1, and by its fore end against an 15 inward step 17 of the needle-covering sleeve 14. The rest of the needle-covering sleeve 14 may be as thick as the part thereof corresponding to the step 17 or may have angularly spaced longitudinal inner ribs 114, in such a way that it may be slidably guided on the outer 20 wall of the syringe barrel 1.

At each of two diametrically opposite locations, the needle-carrier 4 has a lateral locking projection 28, which projects radially outwardly and is slidably engaged in an associated longitudinal slot 18 of the 25 needle-covering sleeve 14. In the illustrated preferred embodiment, each locking projection 28 consists of a radial pin passing through the outward flap 104 of the needle-carrier 4 and engaging in a hole of the syringe barrel 1, thereby also advantageously anchoring 30 mechanically the needle-carrier 4 to the syringe barrel

1. Nevertheless, each locking projection 28 may be made in any other manner, and may particularly be formed of one piece with the needle-carrier 4 or with its flap 104, without engaging the syringe barrel 1, and then  
5 the needle-carrier 4, 104 will be connected to the syringe barrel 1 by simply force-fitting and/or by gluing or welding.

Each longitudinal slot 18 formed in the needle-covering sleeve 14 has a fore part with a constant  
10 width, connected to a rear part 118, whose width progressively decreases towards the rear end of said needle-covering sleeve 14, and being delimited, at its sides, by two stop sticks 19 formed in the wall of the needle-covering sleeve 14 by providing an appropriately  
15 shaped aperture 20, on the needle-covering sleeve 14. The two stop sticks 19 converge towards the rear end of the needle-covering sleeve 14, each forming a progressively tapering length 118 of the slot. The rear free ends of the two stop sticks 19 are shaped so as to  
20 form each a housing for a locking projection 28 of the needle-carrier 4. In the rest position, the two convergent stop sticks 19 are touching, or almost touching each other with their rear free ends, but may be elastically opened apart, substantially in the  
25 tangential or circumferential direction with respect to the needle-covering sleeve 14 and to such an extent as to allow the passage of each locking projection 28 between their rear free ends, and beyond them, as described hereafter.

30 The above described disposable safety syringe

operates as follows:

In the initial condition, i.e. the user-supplied condition, the different parts of the syringe are in the positions shown in figs. 2 and 3. More precisely, 5 the needle-covering sleeve 14 is in a retracted rest position, in which it leaves the needle 5 exposed, and is held and hooked by the retaining tongues 10, which are set free and thus in their radially retracted position. The locking projections 28, formed of one 10 piece with the needle-carrier 4, are in the fore end part of their respective slots 18 of the needle-covering sleeve 14. The helical spiral spring 16 is compressed and entirely housed in the rear part of the 15 syringe barrel 1. The retaining tongues 10 are preferably as long as to hook and retain the needle-covering sleeve 14 in a retracted position, in which its rear rim is close to the head 7 of the syringe barrel 1, whereby the spring 16 is actually invisible. 20 The plunger 2 and its stem 3 lie in an advanced position, in which the plunger 2 is close to the fore end of the syringe barrel 1, but is still able to run a small forward stroke. The rear head 8 of the stem 3 of the plunger 2 is partially inserted in the rear hollow 25 head 7 of the syringe barrel 1, but is stopped in a position, in which it does not come into contact with the inner slanted projections 15 of the retaining tongues 10, or only touches said projections 15, without exerting any perceptible pressure thereon. In 30 the illustrated embodiment, the head 8 is stopped by

means of a safety flange 21, which extends all around the head 8 of the stem 3 of the plunger 2, for example covering slightly less than 360°, and bears against the rear edge of the hollow head 7 of the syringe barrel 1, thereby stopping the head 8 of the stem 3 of the plunger 2 in the above mentioned position, in which it does not interfere with the inner projections 15 of the retaining tongues 10.

The safety flange 21 is integral with the head 8 of the stem 3 of the plunger 2, through a circumferential weakened line 22 for predetermined breaking and easy tear-off operations, so as to be torn along said line 22 and manually removed before using the syringe. Naturally, the safety flange 21 may be replaced by any other tearable abutment member, similar or equivalent thereto, such as a collar, a ring, or one or more single radial projections.

Once the safety flange 21 is torn off and the protective cap 6 of the needle 5 is removed, the latter may be introduced, for example, in an ampoule containing the to-be-injected liquid, and this liquid may be aspirated in the syringe barrel 1, by pulling the plunger back, by means of the head 8 of the stem 3, and by bringing it to a retracted syringe-filling position. Naturally, the safety flange 21 may be torn off the head 8 of the stem 3 even after aspirating the liquid to be injected, i.e. after filling the syringe, and so said safety flange 21 may be also used to improve the seizure of the head 8 of the stem 3, to pull back the plunger 2.



The syringe being so filled, the injection is made in the usual way, since the needle-covering sleeve 14 is still hooked and held by the retaining tongues 10 in its retracted rest position, as shown in fig. 3, in which it leaves the needle 5 exposed. In the final part of the injection stroke of the plunger 2, the head 8 of the stem 3, which now has no abutment by the safety flange 21, penetrates in the hollow head 7 of the syringe barrel 1 more deeply than before, for example up to the bottom of said head 7, or anyway to such an extent as to engage and push radially outwardly the inner projections 15 of the retaining tongues 10, and as to radially open, i.e. as to outwardly angularly deflect said retaining tongues 10, as shown in fig. 5. While being opened apart, the retaining tongues 10 release the needle-covering sleeve 14, which is pushed by the spring 16 and advanced on the syringe barrel 1 until it adheres with its fore end against the part of the patient body, in which the needle 5 is inserted. Then, while the needle 5 is extracted from the patient body, the needle-covering sleeve 14 is further advanced with respect to the syringe barrel 1 by the spring 16, until it reaches a final advanced safety position, in which besides entirely covering the needle 5, it also extends beyond the pointed end thereof, to such an extent as to prevent the needle to be accessed by a finger, as shown in figs. 4 and 5.

During the above described axial forward movement of the needle-covering sleeve 14, the lateral locking projections 28 of the needle-carrier 4, 104, slide at

first in their respective slots 18 having uniform width and then in the slots 118, associated thereto, progressively narrowing between the convergent stop sticks 19, thereby elastically opening said sticks 19  
5 apart. A short while before the plunger 2 reaches the end of its injection stroke and the stem 3 is stopped by the abutment of its head 8 against the bottom of the hollow head 7 of the syringe barrel 1, as shown in fig. 5, the lateral projections 28 of the needle-carrier 4,  
10 104 pass between the rear free ends of their respective stop sticks 19, and carry with them these ends of said stop sticks 19, which elastically close, i.e. approach again before the locking projections 28, and lock them to the needle-covering sleeve 14, as shown in fig. 4.  
15 Particularly, each locking projection 28 is caught between the approached or joined free ends of their respective stop sticks 19 and the rear transverse edge of the shaped aperture 20. By this arrangement, the needle-covering sleeve 14 is fastened to the needle-  
20 carrier 4, 104 and- in the illustrated embodiment - also to the syringe barrel 1, in its advanced safety position, in which it entirely covers the needle 5 and prevents it from being accessed. In these conditions, any reuse of the syringe for another injection is  
25 impossible. The attempt to forcibly slip axially the needle-covering sleeve 14 either forward or backward would cause the fore end of the syringe barrel 1 and/or the needle-carrier 4, 104 to break, or - when the lateral locking projections 28 are only integral with  
30 the needle-carrier 4, 104 - would cause not only the

needle-covering sleeve 14, but also the needle-carrier 4, with the needle 5, to be torn off and removed, with the needle being anyway inaccessibly held inside the needle-covering sleeve 14 and being linked thereto.

5           The embodiment of the syringe illustrated in figs. 6 to 14 mostly corresponds to that according to figs. 1 to 5. Like or equivalent parts are designated by the same reference numerals, the above description with reference to figs. 1 to 5 being applicable, as regards  
10 construction and operation. The differences between the embodiment of figs. 6 to 14, and the embodiment of figs. 1 to 5 will be only described hereafter.

Particularly, in the embodiment according to figs. 6 to 14, the head 8 of the stem 3 has a peripheral  
15 annular extension 108, on the side connecting it to the stem 3, having a predetermined axial thickness and being adapted to form an outward annular shoulder. The latter is meant to cooperate with the projections 15  
20 14, both for causing them to be opened out, when the sleeve 14 is in the disengaged position, and for engaging the rear part of the peripheral annular shoulder 108 of the stem head 8, which is locked and cannot move neither backward nor forward between the  
25 projections 15 and the rear widened end of the syringe barrel 1. Hence, the tongues 10 are used as means for retaining the sleeve 14 during the injection, and the plunger in its utmost penetration position inside the syringe barrel 1.

30           Moreover, according to a further characteristic,

the plunger stem 3 is made to be substantially telescopically extensible, there being provided means for fixing the different length adjustments of the stem 3.

5       With particular reference to figures 6 to 10, the stem has a circular cross section and is composed of two parts, which are axially movable, relative to each other. The two parts 103 and 203 have cooperating radial means 303, 403, for locking the two parts 103,  
10   203 in the selected position. Advantageously, one stem part 103 has a longitudinal groove 503, which provides it with a U-shaped cross section, and is the engagement seat for the other stem part 203, having a complementary shape, and such as to complete the cross  
15   section of the part 103, forming therewith a complete circular section. At the bottom of the engagement seat on the side opposite to the open side, the part 103 has regularly and predeterminedly spaced notches or apertures 303, whereas on the side associated thereto,  
20   the second stem part 203 has complementary teeth 403.

Thanks to the above expedients, it is possible to select, during manufacture, the desired length of the stem 3, by varying the relative position of the two stem parts 103, 203. The complementary non round shape  
25   of the housing groove 503 and of the stem part 203 is such as to prevent mutual rotation thereof. The notches or apertures 303 and the projections 403 allow the two stem parts 103, 203 to be fixed with respect to a mutual axial movement thereof, whereas the mutual  
30   engagement of the two parts 103, 203 is remarkably

simple. The projections 403 and the total diameter of the stem 3 have such radial dimensions, possibly by also making use of axial guide ribs, that when the stem 3 is fitted in the syringe barrel 1, the two stem parts 103, 203 are stably linked to each other, any dimensional tolerances required to allow the stem 3 to slide being also considered.

The inside diameter of the needle-covering sleeve 14 is, for a certain length of the rear end portion thereof, greater than the outside diameter of the syringe barrel 1, and the cylindrical hollow space resulting therefrom houses the helical spiral spring 16, which bears by its rear end against the radial tabs 11 of the syringe barrel 1 and against the bottom of the hollow head 7 of the syringe barrel 1, and by its fore end against an inward step 17 of the needle-covering sleeve 14. The rest of the needle-covering sleeve 14 may be as thick as the part thereof corresponding to the step 17 or may have angularly spaced longitudinal inner ribs 114, in such a way that it may be slidably guided on the outer wall of the syringe barrel 1.

In the embodiment according to figs. 6 to 14, while the sleeve 14 snaps forwards, the head 8 of the stem 3 advances to the position in which it hooks the outward peripheral annular shoulder 108 by the teeth 15 and the head 8, the stem 3 and the plunger 2 are kept locked so that they cannot move in either longitudinal direction of the syringe barrel 1.

When the stem 3 is substantially as long as the

syringe barrel, or anyway adapted thereto, the greatest possible quantity of to-be-injected liquid can be aspirated. In this case, as shown in figs. 8 and 9, before disengaging the sleeve 14 and bringing the plunger 2, i.e. the stem 3 into the position in which they are secured to the syringe barrel 1, the whole volume of liquid aspirated by the syringe is to be injected. As previously explained, when the injection of smaller doses with respect to the greatest quantity of liquid which may be aspirated by the syringe is sufficient, this configuration according to figures 8 and 9 does not ensure an unshared use thereof.

Therefore, the configuration illustrated in figures 8 and 9, is intended to be used when a single person, or any other patient must be injected with the whole maximum volume of liquid which may be aspirated.

In order to obtain a disposable syringe even when the dose to be injected is smaller than the maximum volume that can be aspirated, the length of the stem 3 must only be shortened. So, in the starting position, the plunger 2 will be in a backward intermediate position in the syringe barrel 1. The whole must be dimensioned so that the suction stroke allows to draw in a quantity of liquid being greater than the quantity to be injected, whereas, once a quantity of air corresponding to the initial volume between the plunger 4 in the starting position and the head of the syringe barrel 1 is discharged, it is possible to inject a dose of liquid being smaller than the quantity drawn in. Thanks to the shortening operation, the head 8 of the

stem 3 can cooperate with the retaining tongues 10 before the whole drawn liquid is injected, and after the predetermined dose is injected.

This operation is shown in figures 11 to 14. These 5 figures illustrate the extreme case, opposite to that of figures 7 to 9. In figures 11 to 14, the stem 3 has the minimum possible length. This length is such that, after the liquid having been aspirated (fig. 12) and air having been discharged (fig. 13), the possible 10 injection stroke with that syringe corresponds to the smallest injectable dose, i.e. substantially to the axial length of the hollow head 7 of the syringe barrel 1.

If the length of the stem 3 is intermediate 15 between the maximum as in figures 7 to 9, and the minimum, as in figures 11 to 14, the injectable dose may be varied as needed.

In any case, the dose predetermined by selecting the length of the stem will only and exclusively be 20 injectable, since when the predetermined dose has been injected, the means for releasing the sleeve 14 and the plunger-clamping means will be unpreventably operated.

CLAIMS

1. A disposable safety syringe, comprising:

a) a cylindrical syringe barrel (1);

b) an injection needle (5), being integral with a  
5 needle-carrier (4, 104), which is attached to the fore  
end of the syringe barrel (1);

c) a plunger (2) which is slidable in the syringe  
barrel (1) and has an injection stroke which extends  
from a retracted utmost syringe-filling position,  
10 wherein the liquid medicine has been aspired, to a  
forwardmost position, and is fitted at its back with a  
manually drivable stem (3), driven out of the syringe  
barrel (1) through the open rear end thereof;

d) a needle-covering sleeve (14), which is axially  
15 fitted on the syringe barrel (1), so as to slide from a  
retracted rest position, in which it leaves the needle  
(5) exposed, into an advanced safety position, in which  
it entirely covers the needle (5);

e) plunger-clamping means, consisting of hook-like  
20 interacting means (12 and 13), which are provided at  
the rear side of the syringe barrel (1) and at the rear  
side of the needle-covering sleeve (14), and are  
initially engaged with each other so as to retain the  
needle-covering sleeve (14) in its retracted rest  
25 position, whereas they are automatically disengaged  
from each other by the stem (3) of the plunger (2), in  
the last portion of the injection stroke of the plunger  
(2), thereby releasing the needle-covering sleeve (14);

f) a spring (16), interposed between the rear of  
30 the syringe barrel (1) and the needle-covering sleeve



(14), which moves the needle-covering sleeve (14), once it is released from the hook-like means (12, 13), towards its advanced safety position, first by making it elastically adhere to the patient body, and then by  
5 progressively advancing it, on extracting the needle (5) from the patient body, at the end of the injection, until it entirely covers the extracted needle (5)

characterized in that

g) the needle-covering sleeve (14) has a rear rim  
10 having the shape of an outwardly projecting hook-like tooth (13), cooperating with one or more complementary inwardly projecting hook-like teeth (12), provided on retaining tongues (10), which extend forwardly in the longitudinal direction of the syringe from a head at  
15 the rear end of the syringe from a head (7) located at the rear end of the syringe barrel (1) and are automatically movable from a radially retracted hooking position, in which their teeth (12) hook the rim (13) of the needle-covering sleeve (14), holding it in its  
20 retracted rest position, into a radially opened out releasing position, in which their teeth (12) are released from the rim (13) of the needle-covering sleeve (14) and disengage it;

h) the rear end of the stem (3) of the plunger (2)  
25 is provided with means (8) which cooperate with the retaining tongues (10) and automatically cause these tongues to move from their radially retracted hooking position, into their radially opened out releasing position, at the end of the injection stroke of the  
30 plunger (2);

i) the needle-carrier (4, 14) has at least one lateral locking projection (28), which projects radially outwards, and slidably engages in a longitudinal slot (18, 118), formed in the needle-covering sleeve (14), whereas, at the rear end of said slot (18, 118), there are provided automatic stop means (19), engaging said lateral locking projection (28), preventing any axial movement thereof with respect to the needle-covering sleeve (14), in the advanced safety position thereof, thus securing at least the needle-carrier (18, 118) to the needle-covering sleeve (14).

2. A syringe as claimed in claim 1, characterized in that the head (7) located at the rear end of the stem (3) of the plunger (2) is hollow and open at its back, and the retaining tongues (10) are formed on the wall of said head (7) by means of cuts (9) and have projections (15) on their inner side, protruding inside the hollow head (7) and cooperating with a head (8), located at the rear end of the stem (3) of the plunger (2) which may penetrate the hollow head (7) of the syringe barrel, lying therein in an initial idle position, in which it is locked by removable safety means (21) and does not act on the inward projections (15) of the retaining tongues (10), which lie in their radially retracted hooking position, and a forward operating position, which is attainable after the removal of the safety means, and in which it pushes the inward projections (15) of the retaining tongues (10) outwards, and moves said tongues (10) into their radially opened out releasing position.

3. A syringe as claimed in claim 2, characterized in that the removable safety means which lock the rear head (8) of the stem (3) of the plunger (2) in its initial idle position, consist of at least one  
5 projection (21), extending around the head (8) of the stem (3) on at least one portion of its perimeter, and cooperating, as an abutment member, with the rear edge of the rear hollow head (7) of the syringe barrel (1), and which projection (21) is connected to the head (8)  
10 of the stem (3) by means of a weakened, predetermined easy tear-off line (22).

4. A syringe as claimed in one or more of the preceding claims, characterized in that the spring (16) is a helical spiral spring and is housed in a hollow  
15 space formed between the rear of the needle-covering sleeve (14) and the syringe barrel (1), bearing by one end against the bottom of the hollow head (7) of the syringe barrel (1), and/or against the radial rear tabs (11) of the syringe barrel (1) and by the other end  
20 against an inward step (17) of the needle-covering sleeve (14).

5. A syringe as claimed in one or more of the preceding claims, characterized in that when the needle-covering sleeve (14) is in the retracted rest  
25 position, the rear rim (13) of said needle-covering sleeve (14) is close to the radial tabs (11), located at the rear end of the syringe barrel (1) and/or close to the rear head (7) of the syringe barrel (1).

6. A syringe as claimed in one or more of the  
30 preceding claims, characterized in that each locking

projection (28) is made of one piece with the needle-carrier (4, 104) or is only fixed to the needle-carrier (4, 104).

7. A syringe as claimed in one or more of claims 1 to 5, characterized in that each locking projection (28) is fastened both to the needle-carrier (4, 104) and to the corresponding fore part of the syringe barrel (1).

8. A syringe as claimed in claim 7, characterized in that the needle-carrier (4) is engaged in the fore end of the syringe barrel (1) and has a flap (104) covering the fore end of the syringe barrel (1), whereas each locking projection (28) consists of a radial pin, passing through the flap (104) of the needle-carrier (4) and engaging in a radial hole of the syringe barrel (1).

9. A syringe as claimed in one or more of the preceding claims, characterized in that the longitudinal slot (18, 118), formed in the needle-covering sleeve (14), in which each locking projection (28) is slidably engaged, progressively tapers, at least in its rear portion (118), towards the rear end of the needle-covering sleeve (14), and this tapering portion (118) thereof is delimited at its sides, by two stop sticks (19) which converge until they are touching, or almost touching each other with their rear free ends, and are formed on the wall of the needle-covering sleeve (14) by means of a shaped aperture (20), while being elastically openable, in the direction tangential or circumferential to the needle-

covering sleeve (14), the whole in such a way that the two stop sticks (19) are opened apart by the locking projection (28) associated thereto, while the needle-covering sleeve (14) is being moved towards its advanced safety position, allowing the passage of the locking projection (28) between their free ends when the needle-covering sleeve (14) has almost reached its advanced safety position, and closing before said locking projection (28), and pointing against it by their now joined free ends, when the needle-covering sleeve (14) has reached its advanced safety position.

10. A syringe as claimed in claim 9, characterized in that - when the needle-covering sleeve (14) is in its advanced safety position - each locking projection (28) is embedded between the rear free joined ends of the convergent stop sticks (19), and a transverse edge, opposite to the shaped aperture (2) formed in the needle-covering sleeve (14).

11. A syringe as claimed in one or more of the preceding claims, characterized in that

k) the cooperating plunger-clamping means (7, 10, 15, 8, 108), provided at the rear end of the plunger stem (3) and of the syringe barrel (1) are arranged to fasten the plunger stem (3) to the syringe barrel (1), so as to prevent it from being unlocked in either longitudinal direction;

l) the stem (3) of the plunger (2) and the syringe barrel (1) are provided at their rear end with cooperating safety means (7, 21), which are manually removable or disengageable, and initially (in the

syringe supplied condition) prevent any forward movement of the stem (3) of the plunger (2), retaining it in a rest or starting position, in which the plunger-clamping means (21), on the stem (3) of the  
5 plunger (2) and on the syringe barrel (1) are disengaged from each other and from which position the stem (3) of the plunger (2) may be caused to run (once the safety means have been released) a terminal forward stroke, substantially corresponding to the minimum  
10 medicine dose which can be injected by the syringe, and thereafter the plunger-clamping means (7, 21) on the stem (3) of the plunger (2) and on the syringe barrel (1) engage with each other and secure the stem (3) of the plunger (2) to the syringe barrel (1);

15 m) the stem (3) of the plunger (2) has a length between

- a maximum length, wherewith, in the initial rest position of the stem (3) of the plunger (2), the fore end of the plunger (2) is set back from the  
20 bottom of the syringe barrel (1), at a distance substantially corresponding to the above mentioned terminal forward stroke of the stem (3) of the plunger (2), and the greatest quantity of medicine that can be injected by the  
25 syringe corresponds to the quantity drawn in, and

- a minimum length, wherewith, in the initial rest position of the stem (3) of the plunger (2), the fore end of the plunger (2) is set back from the  
30 bottom of the syringe barrel (1), at a distance

substantially corresponding to the longest possible further backward stroke of the plunger (2), from this position to the retracted utmost syringe-filling i.e. aspirating position and the greatest quantity of medicine that can be injected by the syringe substantially corresponds to the terminal forward stroke of the stem (3) of the plunger (2) (smallest injectable dose).

10 12. A syringe as claimed in claim 11, characterized in that it is associated to a package of liquid medicine, and the stem (3) of its plunger (2) has such a length that the maximum syringe-filling volume of medicine which can be aspirated is at the most equal to the volume of the medicine contained in the package or preferably smaller.

13. A syringe as claimed in claims 11 or 12, characterized in that syringes for injecting predetermined medicine doses, or smaller, may be provided with different stems (3) having a corresponding fixed length, and being by turns fitted in the syringe barrel (1) during its manufacturing process.

14. A syringe as claimed in claims 11 or 12, characterized in that the stem (3) may be provided with a variable length (103, 203), for example with a telescopic adjustment, which may be fixed in the selected length position (303, 403).

15. A syringe as claimed in claims 11 to 14, characterized in that the safety means between the stem

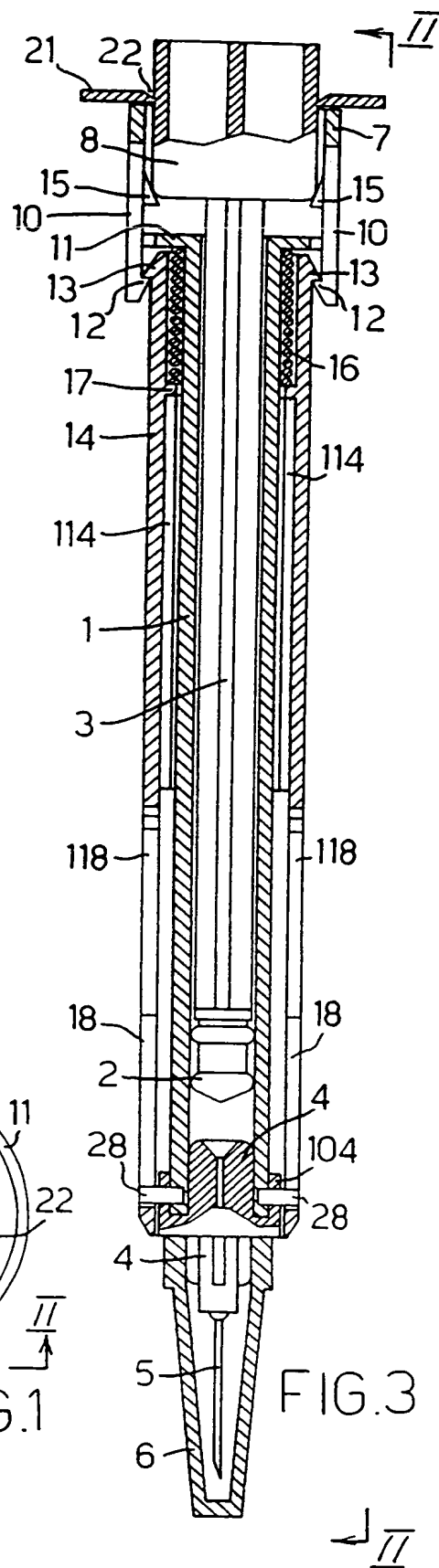
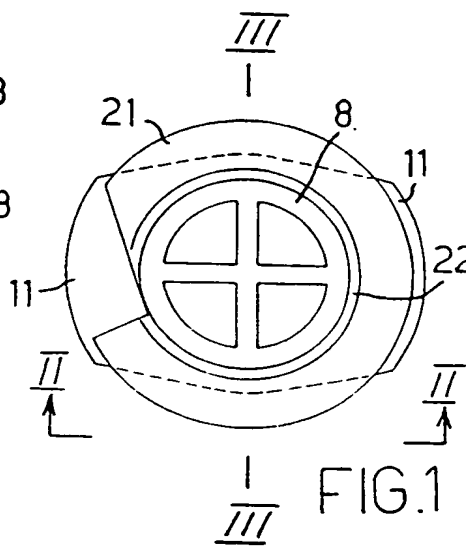
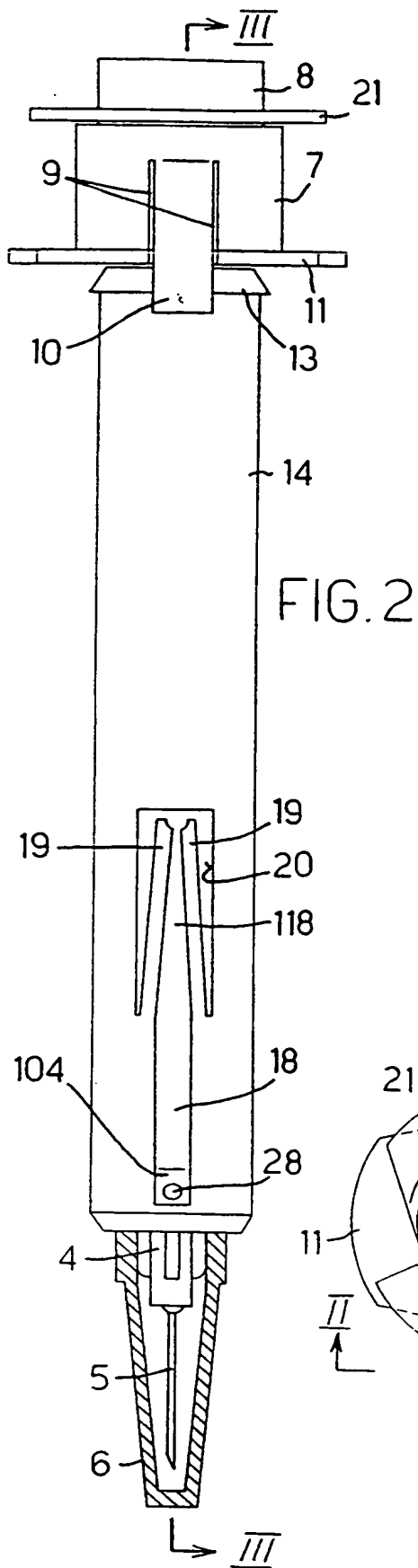
(3) of the plunger (2) and the syringe barrel (1) consist of axial rear abutment extensions (7), associated to the stem (3) or to the syringe barrel (1), particularly preferably to the latter, said axial  
5 abutment extensions (7) cooperating with a radial expansion (21), having the shape of a removable tear-away flange, which is attached to the syringe barrel (1) or to the rear end of the stem (3) of the plunger (2), preferably to the latter, which axial abutment  
10 extensions (7) are radially beyond the maximum radial dimensions (108) of the stem (3) of the plunger (2) or of the syringe barrel (1), whereas the removable radial flange (21) has a radial extension at least equal to or slightly greater than the radial position of the axial  
15 abutment extensions (7) and is connected to the stem (3), or to the syringe body (1) by means of a weakened line (22), and is provided with means for seizing it and tearing it away.

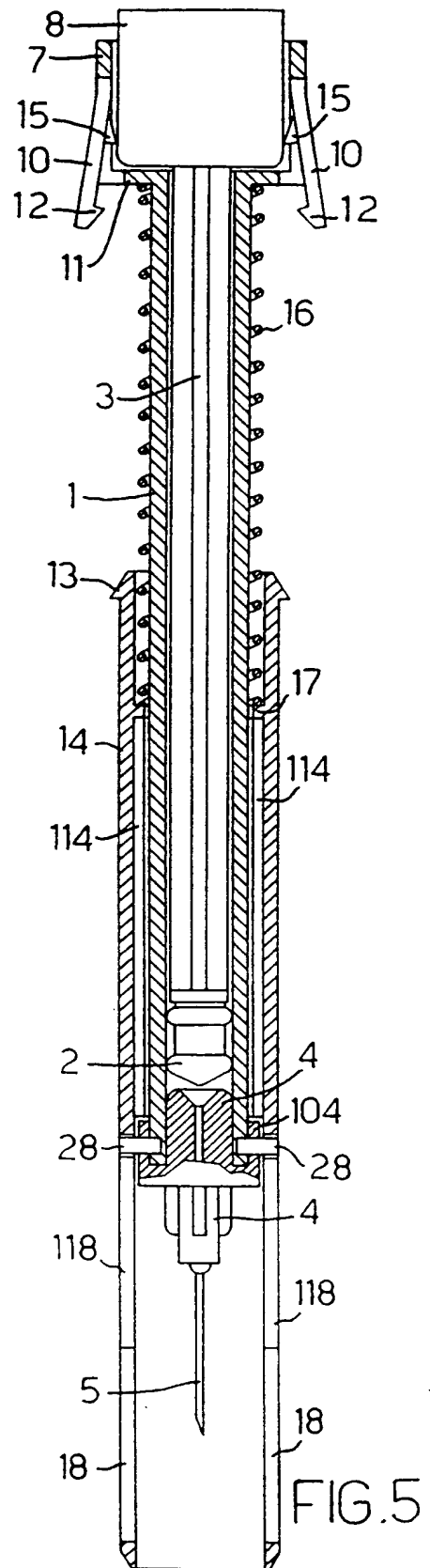
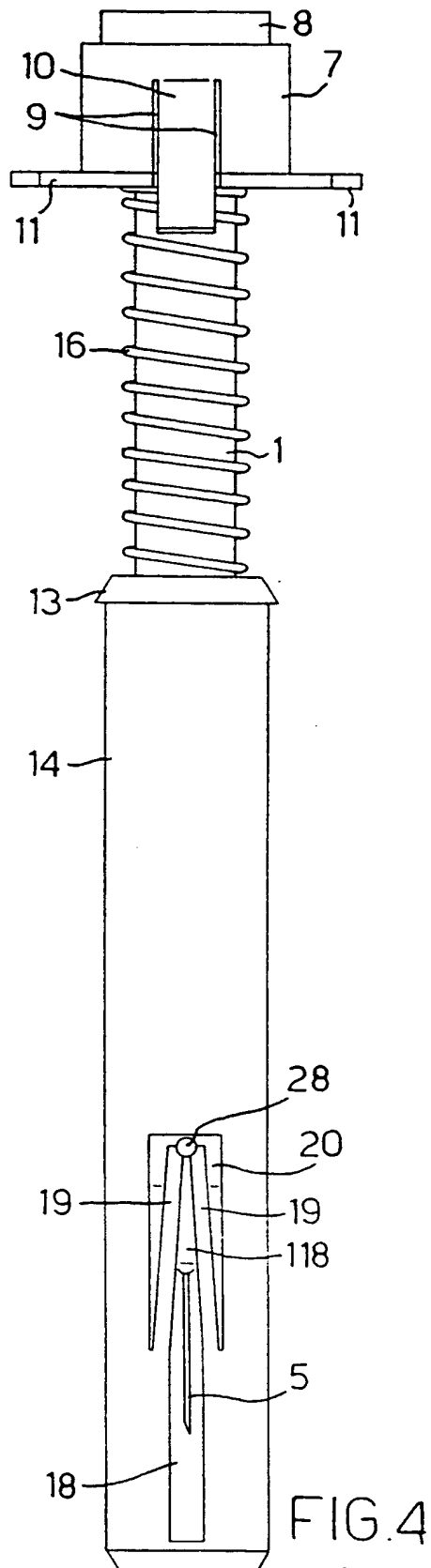
16. A syringe as claimed in claim 15,  
20 characterized in that the syringe barrel (1) has, at its rear end, a widened hollow head (7), there being provided therein at least one, preferably more peripheral radially inwardly protruding teeth (15), whereas the stem (3) also has a complementary widened  
25 terminal head (8), which has at least two radially outward peripheral projections (108), preferably a peripheral outward annular shoulder, being meant to cooperate with the tooth or teeth (15) by engaging therewith by its rear part, through elastic overstress,  
30 whereas at a predetermined distance from the outward

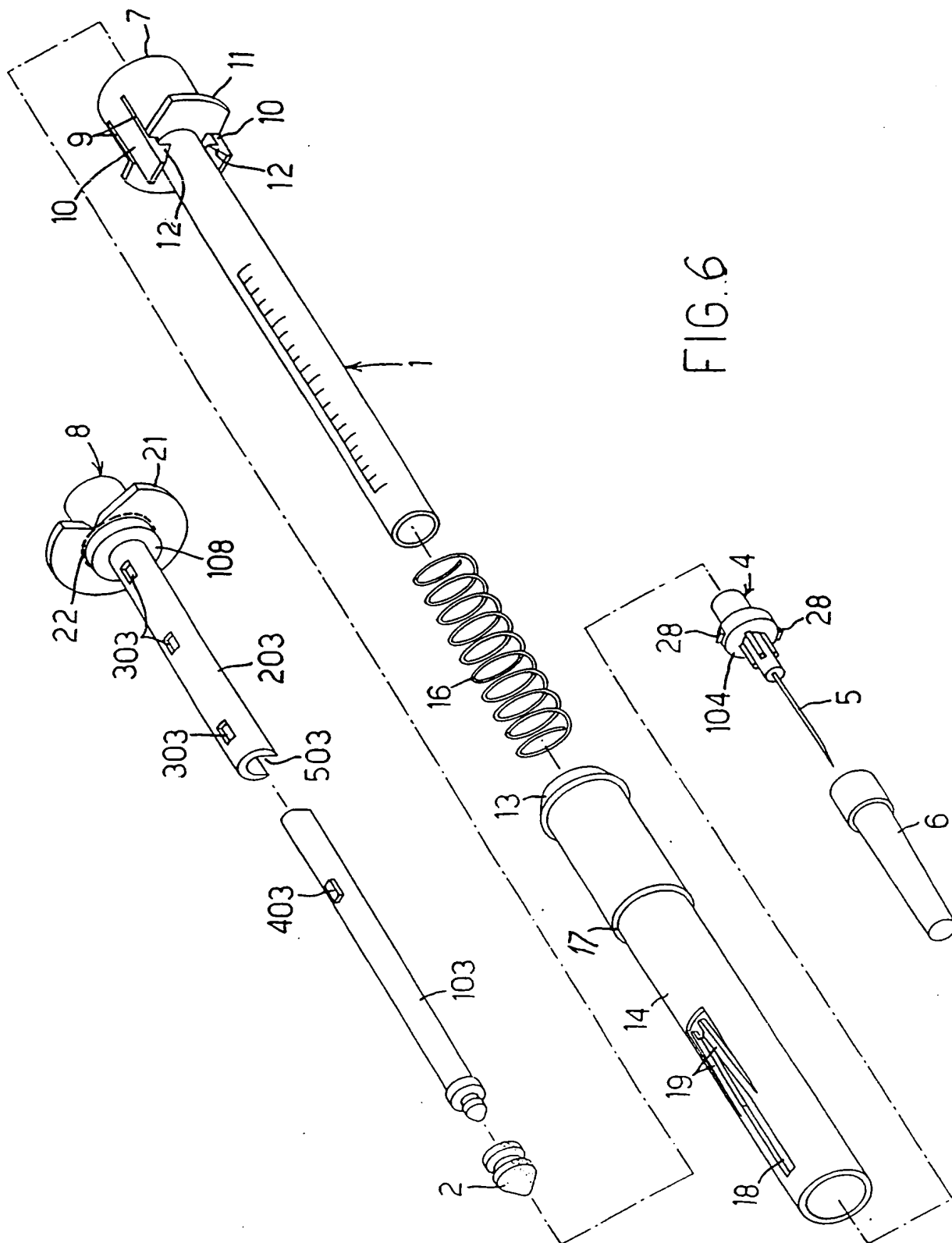


annular shoulder (108), the widened head of the stem (3) bears, by the connection weakened line, an outer radial annular flange (21), which is meant to cooperate with the rear end edge of the hollow head (7) of the syringe barrel (1), and which preferably extends over less than 360°.

17. A syringe as claimed in claim 2, and in one or more of claims 11 to 16, characterized in that the hollow head (7), located at the rear end of the plunger stem (3) has an outward annular shoulder (108) which engages by its rear part with the projections (15), immediately after the needle-covering sleeve (14) release, and is kept fastened to the syringe barrel (1) in a longitudinally unmovable position in either direction.







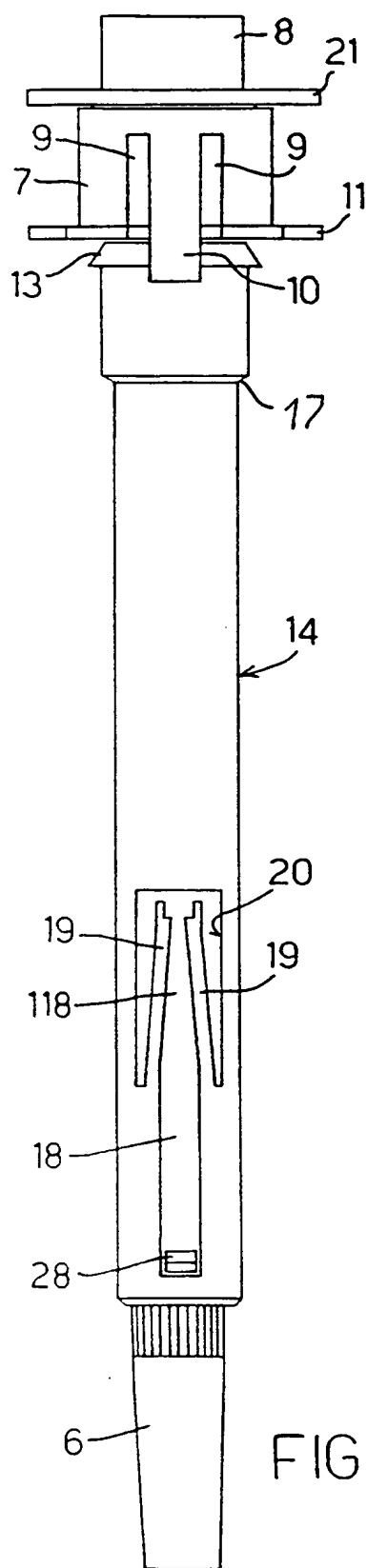


FIG. 7

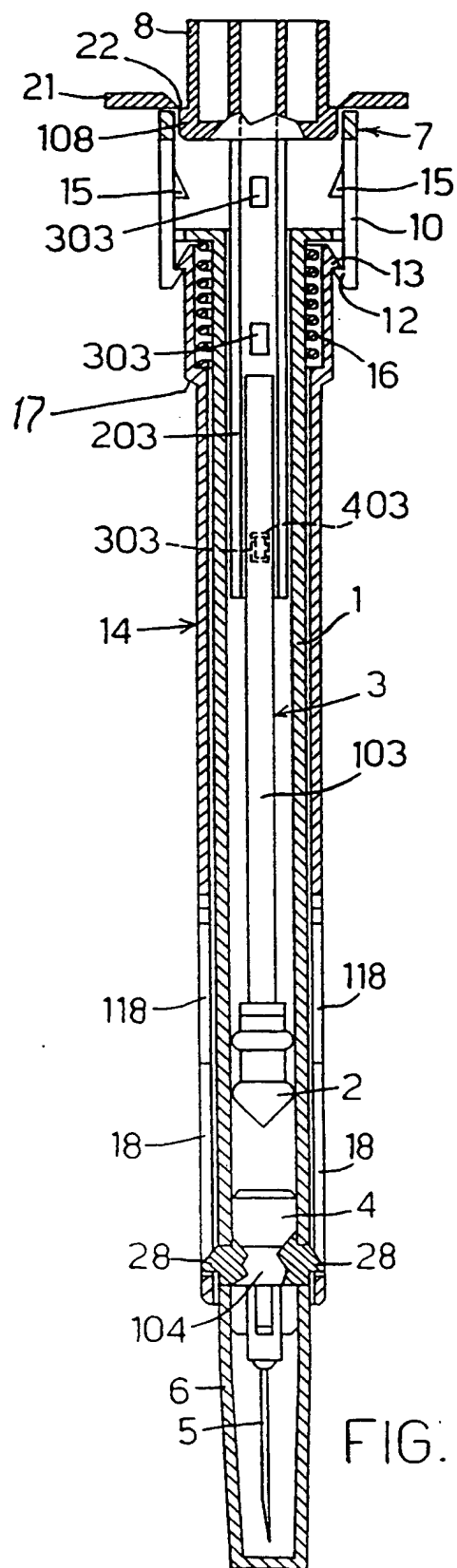


FIG. 8

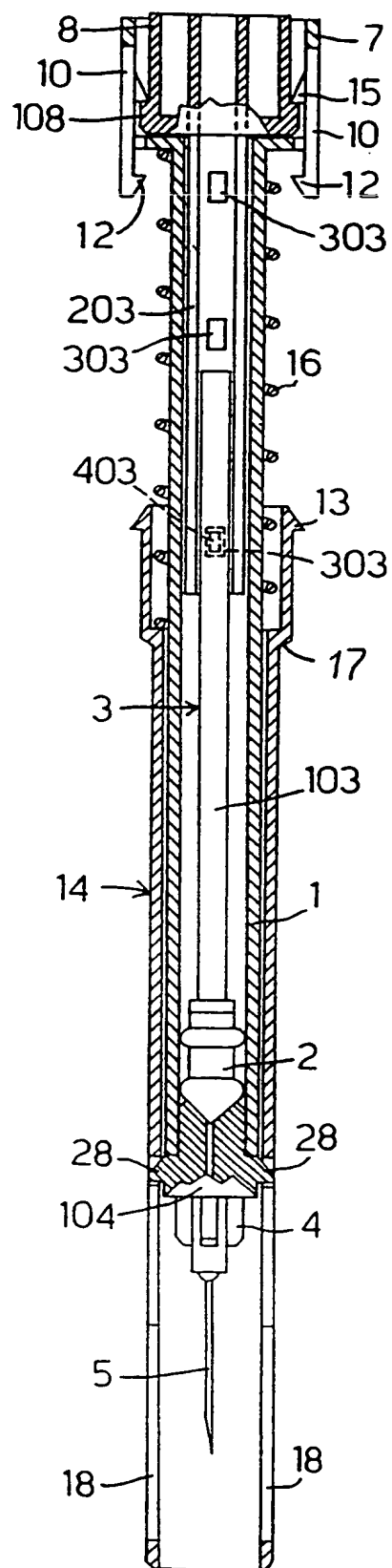


FIG. 9

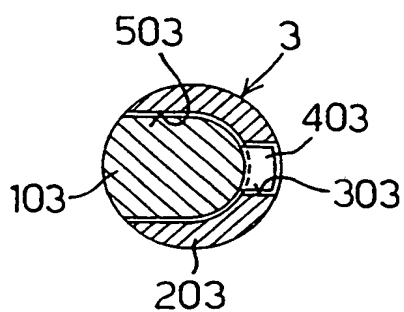
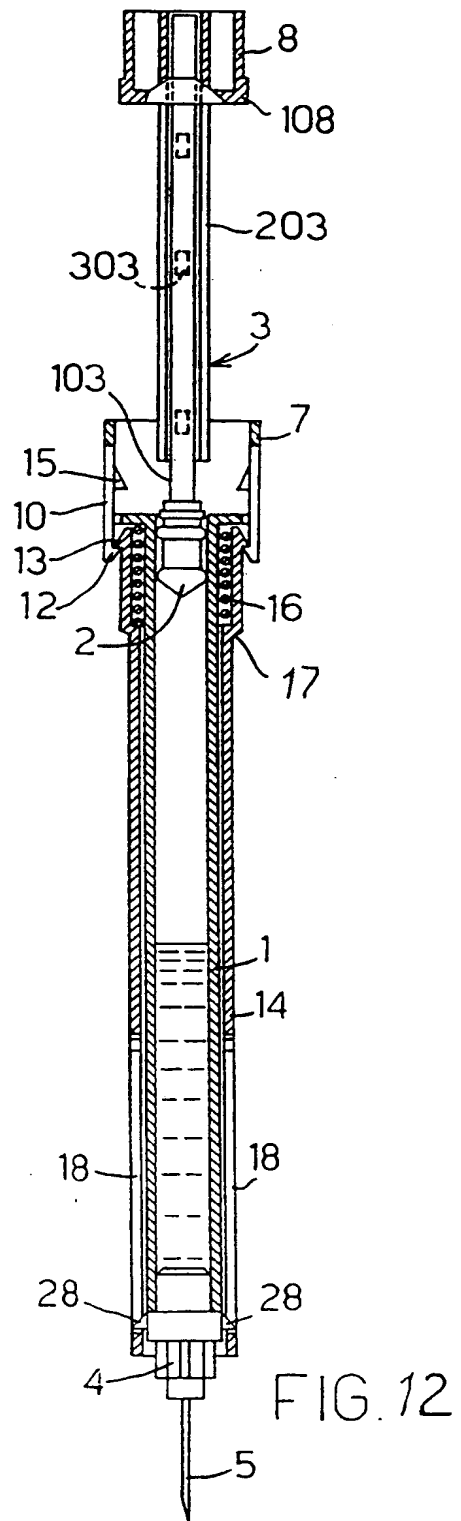
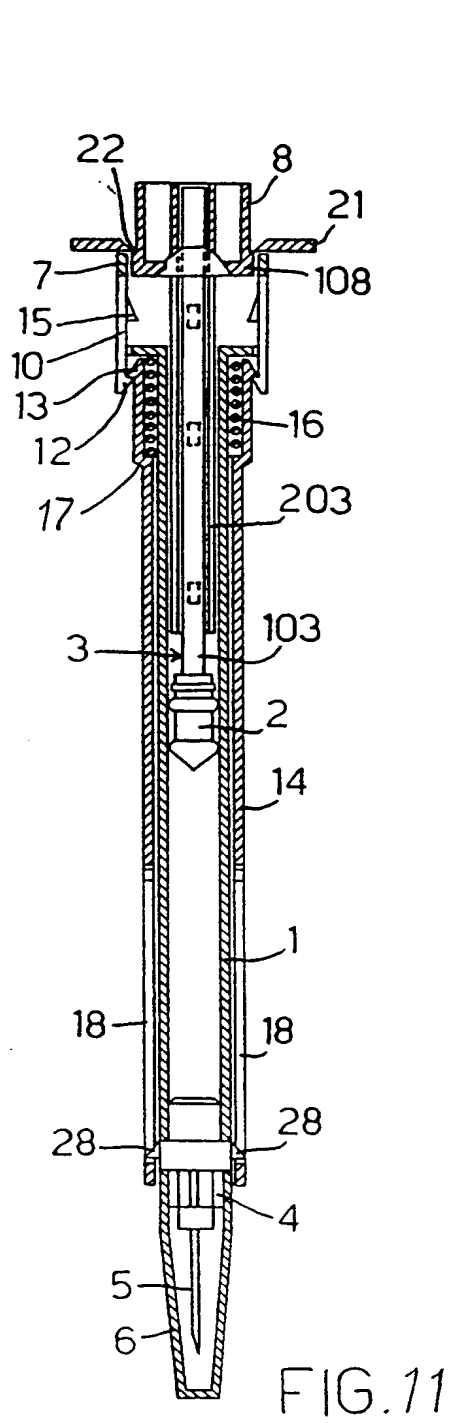


FIG. 10



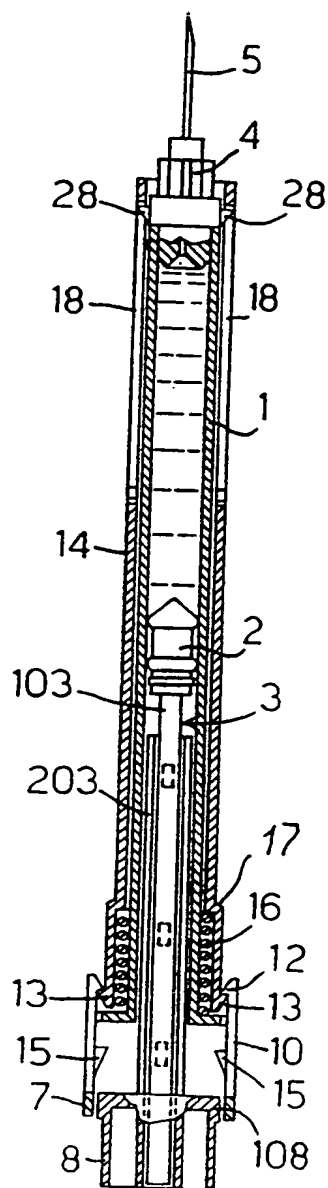


FIG. 13

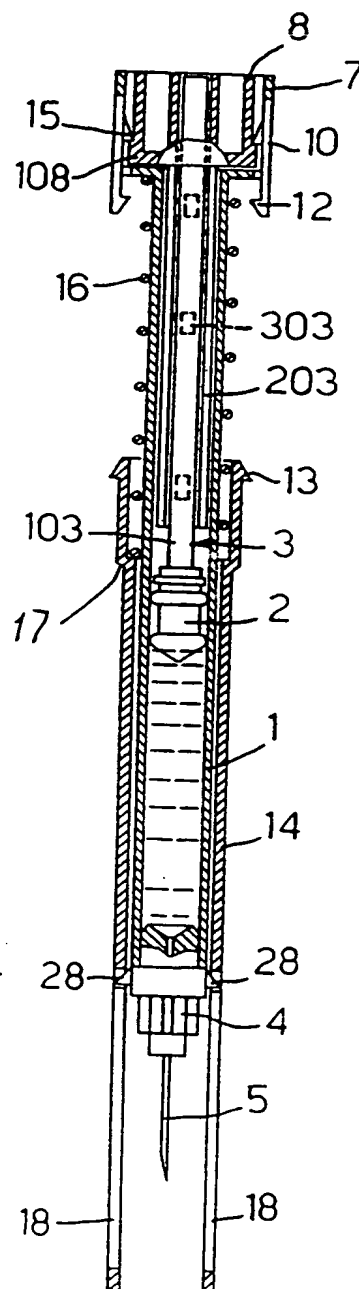


FIG. 14



# INTERNATIONAL SEARCH REPORT

1. National Application No  
PCT/EP 98/00692

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 680 767 A (RIGHI NARDINO ;ROSSI ROBERTO (IT)) 8 November 1995 see the whole document ---	1-17
A	EP 0 467 173 A (RIGHI NARDINO ;ROSSI ROBERTO (IT)) 22 January 1992 see the whole document ---	1-17
A	WO 93 00949 A (IVALDA SPA ;PENTAFERTE SRL (IT); ROMAGNOLI PAOLO (IT)) 21 January 1993 see the whole document ---	1-17
A	US 5 562 626 A (SANPIETRO JOSEPH A) 8 October 1996 see the whole document --- -/--	1-17

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

26 June 1998

Date of mailing of the international search report

06/07/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Clarkson, P

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 98/00692

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 650 187 A (GUERINEAU JEAN ; POIRIERS DOMINIQUE (FR)) 1 February 1991 see the whole document -----	1-17

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 98/00692

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0680767	A	08-11-1995	CA 2123278 A	11-11-1995
			US 5562624 A	08-10-1996
EP 0467173	A	22-01-1992	IT 1243354 B	10-06-1994
			IT 1248101 B	05-01-1995
			AT 129906 T	15-11-1995
			CA 2047263 A,C	20-01-1992
			DE 69114390 D	14-12-1995
			DE 69114390 T	05-06-1996
			DK 467173 T	11-03-1996
			ES 2082052 T	16-03-1996
			FI 913313 A	20-01-1992
			IL 98759 A	31-12-1995
			JP 8010324 A	16-01-1996
			PT 98378 A	30-09-1993
			RU 2079308 C	20-05-1997
			US 5163918 A	17-11-1992
WO 9300949	A	21-01-1993	IT 1253104 B	10-07-1995
			AU 2193892 A	11-02-1993
US 5562626	A	08-10-1996	NONE	
FR 2650187	A	01-02-1991	FR 2648716 A	28-12-1990
			AT 112690 T	15-10-1994
			DE 69013363 D	17-11-1994
			DE 69013363 T	18-05-1995
			DK 519922 T	18-04-1995
			EP 0519922 A	30-12-1992
			ES 2074168 T	01-09-1995
			WO 9113643 A	19-09-1991
			US 5267976 A	07-12-1993
			EP 0405039 A	02-01-1991

